

3. (AMENDED) The implantable device according to claim 1, wherein said [elongated] elongate conduit has a second [elongated] elongate passageway extending from an opening in the conduit forward tip end to a location rearward from said expandable element.

4. (AMENDED) The implantable device according to claim 1, wherein said expandable element is attached onto said [elongated] elongate conduit element by a material comprising an adhesive material.

5. (AMENDED) The implantable device according to claim 1, wherein [said rear port portion has an outside diameter larger than that of] said elongated conduit element permits subcutaneous positioning of the rear port portion.

6. (AMENDED) The implantable device according to claim 1, wherein the [construction material is] implantable device is constructed using a bio compatible material [selected from the group of] such as polyurethane or silicone.

7. (AMENDED) The [the] implantable device according to claim 1 [2], wherein [said elastic septum is retained in said cavity by a clamp ring located around said rear port portion] the rear port portion comprises a compression ring for maintaining a seal of the rear port portion.

8. (AMENDED) An implantable device assembly, [adapted for a device being surgically implanted into body tissue of a patient adjacent to a body lumen for restricting the body lumen, the assembly] comprising:

- (a) an elongate [elongated] guide probe member adapted for being inserted [as a guide means] into tissue adjacent [to an restrictable] a body lumen of a patient;
- (b) an elongate [elongated] implantable device adapted for being surgically implanted into the tissue adjacent to the body lumen, said implantable device including a forward expandable element and a rear port portion connected together by flexible conduit, said conduit having a first inner passageway in fluid communication between said expandable

element and said rear port portion and having a second passageway [arranged for being slidable over] adapted for receiving said elongate [elongated] probe member; and

(c) [a] an external source containing a flowable material and adapted for [being removably connected] connection to the rear port portion of said implantable device, whereby a flowable material from said external source can be introduced through the rear port portion and through the first passageway of said implantable device so as to expand the forward expandable element adjacent a body lumen to at least partially and adjustably restrict the lumen.

9. (AMENDED) The implantable device assembly of claim 8, wherein said guide probe member [is] comprises a stiff elongate [elongated] rod having a pointed forward end.

10. (AMENDED) The implantable device assembly of claim 8, wherein said guide probe member [is] comprises a flexible guidewire.

11. (AMENDED) The implantable device assembly of claim 8, wherein said implantable device rear port portion contains an elastic septum and said source is a syringe having a forward facing needle whereby said needle may be sealingly inserted [through] in said septum and a flowable material injected from said syringe through the first passageway to expand the forward expandable element.

12. (AMENDED) The implantable device assembly of claim 11, wherein said syringe includes an axially movable rear plunger element, whereby the hollow needle is insertable into the elastic septum located in the rear port portion of the implantable device and a flowable material injected by the plunger element through the [follow] hollow needle and first passageway to expand the forward expandable element.

13. (AMENDED) A method for variably restricting a body lumen in a patient, comprising the steps of:

[(a) surgically inserting an elongated probe member into body tissue of a patient to a location adjacent to a body lumen to be restricted;]

[(b)] guiding [providing] an elongate [elongated] implantable device into body tissue of a patient to a location adjacent a body lumen to be restricted using an elongate probe member, the elongate implantable device having an expandable element located at its forward end and having a port portion provided at [is] its rearward end, [sliding an outer passageway of the implantable device along said probe member,] so that the expandable element is positioned adjacent to the body lumen; and

[(c)] providing [injecting] a flowable material from a source into [a said implantable device rear] the port portion, so as to expand the expandable element [sufficient] to at least partially restrict the body lumen [, then removing the source;], wherein the implantable device is guided over the elongate probe member.

[ (d) withdrawing the elongated probe member from the patient's body tissue and from the outer passageway of the implantable device;

(e) positioning said implantable device rear port portion inside the body tissue and near the surface of the skin, and

(f) closing the patient's skin over the device rear port portion.

]

14. (AMENDED) [A] The method [for variably restricting a body lumen in a patient] of claim 13, further comprising the [successive] steps of:

[

(a) surgically inserting an elongated probe member into body tissue of a patient to a location adjacent to a body lumen to be restricted;

(b) providing an elongated implantable device having an expandable element located at its forward end and sliding an outer passageway of the implantable device along the

elongated probe member and positioning the expandable element adjacent to the patient's body lumen;

]

[(c)] withdrawing the elongate [elongated] probe member from the patient's body [tissue and from the outer passageway of the implantable device];

[

(d) injecting a flowable material from a source into a rear port portion of said implantable device, and expanding the expandable element sufficient to at least partially restrict the body lumen, then removing the source;

]

[(e)] positioning the [rear] port portion of said [elongated] elongate implantable device inside the patient's body tissue near the surface of the skin, and

[(f)] closing an opening made in the patient's skin over the [implantable device rear] port portion.

15. (AMENDED) The [body lumen restriction] method of claim 13 [11], wherein the step of providing a flowable material [injected into the implantable device expandable element is selected from the group including] includes injecting one or more of a saline liquid solution, a gel, or a slurry of particles in a fluid carrier.

16. (AMENDED) The [body lumen restriction] method of claim 13, wherein the step of providing a flowable material [is] includes injecting a radiopaque material to facilitate fluoroscopic visualization.

17. (AMENDED) The [body lumen restriction] method of claim 13, wherein the elongate [elongated] probe member and implantable device are surgically inserted to a location adjacent the urethra of a [female] patient.

PRELIMINARY AMENDMENT

Serial Number: 09/477,977

Filing Date: January 5, 2000

Title: IMPLANTABLE DEVICE AND METHOD FOR ADJUSTABLY RESTRICTING A BODY LUMEN

Page 6

Dkt: 825.001US2

B1 conts  
18. (AMENDED) The [body lumen restriction] method of claim [15] 13 including placing an implantable device along two opposite sides of the urethra of a [female] patient.

---

B2  
19. (NEW) The method of claim 13, wherein the implantable device is guided over the elongate probe member.

20. (NEW) The method of claim 13, wherein the implantable device and elongate probe member are inserted into the body tissue as a unit.

21. (NEW) The method of claim 13, wherein the implantable device is positioned using visual guidance.

22. (NEW) The method of claim 13, wherein the implantable device is positioned using fluoroscopy.

23. (NEW) The method of claim 13, further comprising:  
increasing restriction of the body lumen by adding flowable material to the implantable device.

24. (NEW) The method of claim 13, further comprising:  
decreasing restriction of the body lumen by removing flowable material from the implantable device.

25. (NEW) The method of claim 13, further comprising:  
measuring restriction of the body lumen by infusing fluid through the body lumen past a restricted portion of the body lumen and measuring back pressure.

26. (NEW) The method of claim 13, wherein providing a flowable material from a source into the port portion comprises:

injecting the flowable material into a septum of the port portion using a hyperdermic needle.

27. (NEW) The method of claim 13, further comprising:  
expanding the expandable element prior to withdrawal of the elongated probe member.
28. (NEW) A method for variably restricting a body lumen in a patient, comprising:  
guiding an elongate implantable device into body tissue of a patient to a location adjacent a body lumen to be restricted using an elongate probe member, the elongate implantable device having an expandable element located at its forward end and having a port portion provided at its rearward end, so that the expandable element is positioned adjacent to the body lumen; and  
providing a flowable material at the rearward end from a source into the port portion, so as to expand the expandable element to at least partially restrict the body lumen;  
wherein the implantable device is positioned using fluoroscopy.
29. (NEW) The method of claim 28, further comprising:  
withdrawing the elongate probe member from the patient's body;  
positioning the port portion of said elongate implantable device inside the patient's body tissue near the surface of the skin, and  
closing an opening made in the patient's skin over the port portion.
30. (NEW) The method of claim 28, wherein the material includes injecting one or more of a saline liquid solution, a gel, or a slurry of particles in a fluid carrier.
31. (NEW) The method of claim 28, wherein providing a flowable material includes injecting a radiopaque material to facilitate fluoroscopic visualization.
32. (NEW) The method of claim 28, wherein the elongate probe member and implantable device are surgically inserted to a location adjacent the urethra of a patient.

33. (NEW) The method of claim 28, including placing an implantable device along two opposite sides of the urethra of a patient.
34. (NEW) The method of claim 28, wherein the implantable device is guided over the elongate probe member.
35. (NEW) The method of claim 28, wherein the implantable device and elongate probe member are inserted into the body tissue as a unit.
36. (NEW) The method of claim 28, further comprising:  
increasing restriction of the body lumen by adding flowable material to the implantable device.
37. (NEW) The method of claim 28, further comprising:  
decreasing restriction of the body lumen by removing flowable material from the implantable device.
38. (NEW) The method of claim 28, further comprising:  
measuring restriction of the body lumen by infusing fluid through the body lumen past a restricted portion of the body lumen and measuring back pressure.
39. (NEW) The method of claim 28, wherein the step of providing a flowable material from a source into the port portion comprises:  
injecting the flowable material into a septum of the port portion using a hyperdermic needle.
40. (NEW) The method of claim 28, further comprising:  
expanding the expandable element prior to withdrawal of the elongated probe member.

PRELIMINARY AMENDMENT

Serial Number: 09/477,977

Filing Date: January 5, 2000

Title: IMPLANTABLE DEVICE AND METHOD FOR ADJUSTABLY RESTRICTING A BODY LUMEN

Page 9

Dkt: 825.001US2

**CONCLUSION**

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at 612-359-3270 to facilitate prosecution of this application.

Respectfully submitted,

JOHN H. BURTON ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.

P.O. Box 2938

Minneapolis, MN 55402

(612) 359-3270

Date

April 26, 2000

By

Joseph C. Huebsch

Joseph C. Huebsch

Reg. No. 42,673

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Assistant Commissioner of Patents, Washington, D.C. 20231 on April 26, 2000.

Frances Essien

Name

Frances Essien

Signature